Appln No.: 09/557,955
Amendment Dated: August 2, 2003
Reply to Office Action of March 27, 2003

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (cancelled)

2. (previously presented) An assay device according to claim 9, wherein said first specific binding agent is an antibody raised in a first species and said non-specific protein is an immunoglobulin from another species.

3. (previously presented) An assay device according to claim 9, wherein said first specific binding agent is a murine antibody.

4. (previously presented) An assay device according to claim 2, wherein said non-specific protein is a rabbit immunoglobulin.

5. (currently amended) An assay device according to claim 9, additionally comprising as an improvement a second population of ~~said~~ direct particulate label sensitised solely with said non-specific protein.

6. (currently amended) An assay device according to claim 2, wherein the particulate direct label comprises a first ~~coloured~~ set of latex particles of a first color having a diameter less than 0.5 micron, and wherein the particulate direct label is co-sensitised with an anti-hCG murine monoclonal antibody as the first specific binding agent and with rabbit IgG as the non-specific protein.

7. (currently amended) An assay device according to claim 6, additionally comprising as a further improvement a second set of ~~coloured~~ latex particles of the first color ~~same colour as the first coloured latex particles~~ and of diameter less than 0.5 micron, said second set of latex particles being sensitised solely with rabbit IgG, wherein the ratio of said first particles to said second set of particles in the device being at least 2:1.

8. (previously presented) An assay device according to claim 7, wherein said ratio is about 3:1.

9. (currently amended) In an assay device wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result, the improvement wherein said labelled reagent comprises

a particulate direct label co-sensitised with

(i) a first specific binding agent having specificity for an analyte, and

(ii) a non-specific protein which can participates in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished in said detection zone to capture the labelled reagent in the control zone when the device is used.

10. (previously presented) An assay device according to claim 9, wherein said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for said analyte but which does not bind to said non-specific protein, and said control zone contains a specific binding agent which binds said non-specific protein but does not bind said specific binding agent co-sensitised on said particulate direct label.

11. (previously presented) An assay device according to claim 9, wherein said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for hCG, said control zone contains an immobilised anti-rabbit IgG antibody, and said labelled reagent is coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.

12. (previously presented) An assay device for detection of an analyte in a liquid sample, comprising:

(a) a support;

(b) a test line comprising a first specific binding reagent immobilized on the support;

(c) a control line comprising a second specific binding reagent immobilized on the support;

(d) a mobile reagent disposed in the device at a reagent position located upstream from the test line and the control line such that a liquid sample applied to the device transports the mobile reagent from the reagent along the support in a downstream direction through the positions of the test line and the control line,

wherein the mobile reagent comprises a direct particulate label co-sensitized with

a third specific binding reagent having specificity for the analyte, and

a protein which is specifically bound by the second specific binding agent but does not bind to the first specific binding agent nor otherwise participate in complex formation which would lead to capture of the mobile reagent in the test line, and

wherein the first specific binding agent specifically binds to the analyte.

13. (previously presented) The assay device of claim 12, wherein the first specific binding reagent is an antibody raised against the analyte.

14. (previously presented) The assay device of claim 13, wherein the protein is an immunoglobin and the second specific binding reagent is an antibody raised against the immunoglobin.

15. (previously presented) The assay device of claim 14, wherein the third specific binding reagent is an anti-human chorionic gonadotropin antibody.

16. (previously presented) The assay device of claim 15, wherein the immunoglobulin is rabbit immunoglubulin G, and the anti-human chorionic gonadotropin antibody is a murine monoclonal antibody.

17. (previously presented) The assay device of claim 16, wherein the direct particulate label is a colored latex particle.

18. (previously presented) The assay device of claim 12, wherein the third specific binding reagent is an anti-human chorionic gonadotropin antibody.

19. (previously presented) The assay device of claim 18, wherein the immunoglobulin is rabbit immunoglubulin G, and the anti-human chorionic gonadotropin antibody is a murine monoclonal antibody.

20. (previously presented) The assay device of claim 19, wherein the direct particulate label is a colored latex particle.